(19)

No. 96-188

In The

Supreme Court of the United States

October Term, 1996

GENERAL ELECTRIC COMPANY, *et al.*,

Petitioners,

vs.

ROBERT K. JOINER and KAREN P. JOINER,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF OF *AMICUS CURIAE* TRIAL LAWYERS FOR PUBLIC JUSTICE IN SUPPORT OF RESPONDENTS

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INTEREST OF THE *AMICUS CURIAE*[1]

Trial Lawyers for Public Justice ("TLPJ") is a national public interest law firm that specializes in precedent-setting and socially significant civil litigation and is dedicated to pursuing justice for the victims of corporate and governmental abuses. Litigating throughout the federal and state courts, TLPJ prosecutes cases designed to advance consumers' and victims' rights, environmental protection, product safety, civil rights and civil liberties, access to our civil justice system, and the protection of the poor and the powerless.

TLPJ acknowledges and supports the role of trial judges in ensuring the integrity of the court system by screening scientific expert testimony for threshold admissibility purposes. TLPJ is concerned, however, that the limited "gatekeeping" function assigned to trial judges by this Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) has been misinterpreted and misapplied by some district courts to prohibit juries from considering reliable and relevant expert testimony. TLPJ is concerned that, in performing the inquiry required by *Daubert*, a number of trial judges — with the encouragement of opponents of the admission of scientific evidence such as Petitioners and their *amici* — have assumed the roles of jurors and "amateur scientists" in rejecting expert testimony with which they disagree, effectively barring the victims of mass torts and toxic exposures from the courthouse.

Although the question before this Court is the appropriate

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1. Pursuant to Rule 37.6 of the Rules of the Court, counsel for a party did not author this brief in whole or in part and no person or entity, other than the *amicus curiae*, its members, or counsel, have made a monetary contribution to the preparation or submission of the brief. Pursuant to Rule 37.3 of the Rules of the Court, the parties have consented to the filing of this brief. Their letters of consent have been filed with the Clerk of the Court.

standard of appellate review of district court decisions excluding scientific testimony under *Daubert*, Petitioners and their *amici* argue at length for a drastically restrictive and self-serving interpretation of the *Daubert* principles. They effectively urge adoption of a new heightened standard for the admissibility of expert scientific testimony. TLPJ submits this brief for the purpose of responding to the erroneous interpretation of the *Daubert* standards advanced by Petitioners and their *amici*. TLPJ urges the Court to re-emphasize the limited "gatekeeping" function of trial judges. In so doing, the Court will provide necessary and timely guidance to litigants and district courts, and will greatly aid the task of appellate review.

SUMMARY OF ARGUMENT

> Trial judges must exercise sound discretion as gatekeepers of expert testimony under *Daubert*. [Defendant], however, would elevate them to the role of St. Peter at the gates of heaven, performing a searching inquiry into the depth of an expert witnesses's soul — separating the saved from the damned. Such an inquiry would inexorably lead to evaluating witness credibility and weight of the evidence, the ageless role of the jury.

McCullock v. H.B. Fuller Company, 61 F.3d 1038, 1045 (2nd Cir. 1995).

In *Daubert v. Merrell Dow Pharmaceuticals*, this Court held that the Federal Rules of Evidence "relaxed" the traditional standard for the admissibility of expert scientific testimony and established a limited gatekeeping role for district courts pursuant to which trial judges should determine only whether proffered

scientific testimony is "reliable" and "relevant." The Court held that scientific testimony is reliable if the expert's "methodology" is sound. The Court stressed that the methodology inquiry is a "flexible one," which should not include an assessment of the correctness of the expert's conclusions. The Court further held that expert scientific testimony is relevant if it will assist the trier of fact to understand the evidence or to determine a fact in issue. Finally, the Court stressed the distinction between the admissibility and the "sufficiency" of scientific testimony, pointing out that the jury system is the appropriate forum for addressing challenges to the sufficiency of such testimony through cross examination, presentation of contrary evidence, and careful jury instructions.

Contrary to the arguments of Petitioners and their *amici*, the United States Court of Appeals for the Eleventh Circuit properly interpreted and applied the Federal Rules and *Daubert*. The Eleventh Circuit carefully followed this Court's instruction that the Federal Rules provide the framework for determining the admissibility of expert testimony; that under the "liberal thrust" of the Federal Rules, traditional barriers to opinion testimony have been "relaxed"; that to be admissible, expert scientific testimony must only be "reliable" and "relevant"; that expert scientific testimony is reliable if the expert's "methodology" is sound; that the methodology inquiry is a "flexible one," which must focus on the expert's reasoning and not upon his conclusions; that expert scientific testimony is relevant if it will assist the jury in determining facts in dispute; and, that the trial judge's gatekeeping responsibility does not extend to assessing the sufficiency of a litigant's evidence or rendering scientific opinions.

Petitioners and their *amici* ignore *Daubert*'s teachings. Disregarding what *Daubert* actually said, they seek to turn the case on its head and create a heightened standard for the

admissibility of expert scientific testimony that would essentially require judges to act as jurors and "amateur scientists." Petitioners and their *amici* act as if the Court in *Daubert* rejected the liberal thrust of the Federal Rules of Evidence and imposed new "formidable burdens" on the proponents of expert testimony, requiring that judges subject such testimony to "more penetrating pretrial scrutiny." *Daubert*, however, did nothing of the sort.

Petitioners and their *amici* act as if *Daubert* held that the admissibility of a scientist's testimony depends upon the correctness or general acceptance of his conclusions, ignoring this Court's instruction that the focus should only be on the expert's methodology. Disregard of this Court's admonition that the "focus" of the reliability assessment be "solely on principles and methodology, not on the conclusions that they generate," would impermissibly permit (if not obligate) trial judges to decide the correctness of an expert's opinions, nullify the "ageless role of the jury," and encourage jurists to act as "amateur scientists." As the Eleventh Circuit properly observed, trial judges must be "careful not to cross the line between deciding whether the expert's testimony is based on 'scientifically valid principles' and deciding the correctness of the expert's conclusions . . . the gatekeeping responsibility of the trial courts is not to weigh or choose between conflicting scientific opinions, or to analyze and study the science in question in order to reach its own scientific conclusions." *Joiner v. General Electric Co.*, 78 F.3d 524, 530 (11th Cir. 1996).

Petitioners and their *amici* act as if *Daubert* established a definitive set of factors for trial courts to use in determining whether an expert's methodology is reliable. Although this Court emphasized that the methodology inquiry is to be a "flexible one," and that many factors might bear on the analysis, Petitioners and their *amici* argue that the four factors discussed in the Court's "general observations" about what may constitute

reliable methodology — testability, publication/peer review, error rate and general acceptance — must be satisfied in order for scientific testimony to be admissible. Such an "inflexible" approach is incompatible with this Court's instruction in *Daubert*, and would prevent reliable and relevant scientific testimony from being heard by juries.

Petitioners and their *amici* also act as if *Daubert* authorized trial judges to exclude scientific testimony from evidence if they find it unpersuasive, ignoring the critical distinction between the admissibility and the sufficiency of scientific testimony. Unlike the admissibility determination, the sufficiency inquiry, which asks whether the collective weight of a litigant's evidence is adequate to present a jury question, lies further down the "litigational road." Petitioners and their *amici* would take a short cut down that road to have judges determine the merits of an expert's conclusions and the weight of the totality of a plaintiff's evidence in the context of lengthy and costly pre-jury trial bench trials on the ultimate question of causation. Such an approach is at odds with *Daubert*, and would essentially require the re-drafting of the Federal Rules.

To achieve judicial uniformity in admitting expert scientific testimony, to avoid the inappropriate exclusion of reliable and relevant testimony, and to preserve the jury-adversarial system as the means of resolving factual disputes, the Court should take this opportunity to re-emphasize the limited nature of the trial judge's gatekeeping function. Trial judges should not perform "a searching inquiry" into an expert's conclusions or "witness credibility and weight of the evidence" — rather, they should decide the admissibility of scientific expert testimony pursuant to the language and spirit of the Federal Rules and the instruction of this Court in *Daubert*.

ARGUMENT

I.

IN *DAUBERT*, THIS COURT HELD THAT THE FEDERAL RULES "RELAXED" THE TRADITIONAL STANDARD FOR THE ADMISSIBILITY OF EXPERT SCIENTIFIC TESTIMONY AND ESTABLISHED A LIMITED GATEKEEPING ROLE FOR TRIAL JUDGES.

In *Daubert*, this Court articulated a new and "relaxed" procedure for determining the admissibility of expert scientific testimony. The essential points of *Daubert* are as follows:

- Fed. R. Evid. 104(a) and 702 provide the framework for determining the admissibility of expert scientific testimony in federal courts. *Daubert*, 509 U.S. at 587-593.

- This Court rejected the defendant's argument that the "general acceptance" test articulated in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923) should govern the admissibility analysis, and agreed with the plaintiff that the standard for admissibility should not be so "rigid." *Daubert*, 509 U.S. at 587-588.

- The Court concluded that the "rigid general acceptance requirement would be at odds with the liberal thrust of the Federal Rules and their general approach of relaxing the traditional barriers to 'opinion' testimony." *Daubert*, 509 U.S. at 588.

- In rejecting the general acceptance test advocated by the defendant, the Court ruled that Rule 702 requires trial judges to ensure, in their "gatekeeping role," only that the proffered scientific testimony is "reliable" and "relevant." *Daubert*, 509 U.S. at 590-591.

- The Court stated that "reliability" turns on whether the expert's "methodology" is sound. The Court emphasized that the judge's "focus, of course, must be solely on principles and methodology, not on the conclusions they generate." *Daubert*, 509 U.S. at 595.

- Although the Court offered "general observations" that could bear upon the "reliability" of scientific evidence, the Court stressed that "[m]any factors will bear on the inquiry, and we do not presume to set out a definitive checklist or test," and "emphasized" that the inquiry is a "flexible one." *Daubert*, 509 U.S. at 593-594.

- The Court held that expert scientific testimony is "relevant," or "fits," if it relates to an issue at hand, *i.e.*, if it will "assist the trier of fact to understand the evidence or to determine a fact in issue." *Daubert*, 509 U.S. at 591.

- The Court noted the defendant's concern that adopting a more "relaxed" approach to the admission of scientific testimony would prompt "befuddled juries" to be "confounded by absurd and irrational pseudoscientific assertions," but said the defendant "seems to us to be overly pessimistic about the capabilities of the jury and of the adversary system generally. Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 595-96.

- The Court also noted that if the "scintilla of evidence presented" is "insufficient," a trial judge "remains free to direct judgment" or "grant summary judgment" under the standards applicable to those "conventional devices," but not to resort to "wholesale exclusion" under Rule 702. *Daubert*, 509 U.S. at 596.

II.

THE ELEVENTH CIRCUIT PROPERLY APPLIED *DAUBERT*'S TEACHINGS.

Petitioners and their *amici* argue the Eleventh Circuit misstated and misapplied the requirements of Rule 702 and *Daubert*. *See, e.g., Brief for Petitioners* at 45 (claiming the Eleventh Circuit "misunderstood the requirements of Rule 702 and misapplied *Daubert*"); *Brief Of The Dow Chemical Company* at 13 (arguing "the court of appeals endorsed an interpretation of *Daubert* and the Federal Rules of Evidence that is erroneous as a matter of law"); *Brief Of The American Medical Association* at 5, 9-10 (asserting the "criteria applied by the Eleventh Circuit are inconsistent with *Daubert*," and that the "court of appeals improperly limited the factors that may be considered by a district court in determining the admissibility of expert testimony"); *Brief Of The Chemical Manufacturers Association* at 14 (arguing the Eleventh Circuit erred in "seriously misinterpreting and misapplying *Daubert*'s core holding"). In fact, however, the Eleventh Circuit accurately defined and applied the *Daubert* admissibility test:

- Following *Daubert*, the Eleventh Circuit observed that the Federal Rules of Evidence "superseded the *Frye* general acceptance test," and that the Rules "introduced a more liberal approach to the question of admissibility of scientific evidence." *Joiner*, 78 F.3d at 529.

- Citing *Daubert*, the Eleventh Circuit stated "the critical concerns of Rule 702 are evidentiary reliability and relevancy." *Joiner*, 78 F.3d at 529.

- Following *Daubert*, the Eleventh Circuit stated that, in assessing the "reliability" of expert scientific testimony, the

"district court must examine the reasoning or methodology underlying the expert opinion," but must "be careful not to cross the line between deciding whether the expert's testimony is based on 'scientifically valid principles' and deciding upon the correctness of the expert's conclusions. The latter inquiry is for the jury. . . ." *Joiner*, 78 F.3d at 530.

- The Eleventh Circuit recounted this Court's "general observations" that could bear on the reliability inquiry and, in accord with *Daubert*'s cautionary language, held that the "factors are neither exhaustive nor applicable in every case." *Joiner*, 78 F.3d at 530.

- Consistent with *Daubert*, the Eleventh Circuit explained that the "relevance" or "fit" requirement is determined by "whether expert testimony offered in the case in sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Joiner*, 78 F.3d at 530.

- In light of *Daubert*'s emphasis upon the jury trial as the appropriate forum for determining the sufficiency of an expert's testimony, the Eleventh Circuit stated that in "analyzing the admissibility of expert testimony, it is important for trial courts to keep in mind the separate functions of judge and jury," and stressed that "the gatekeeping role" is "not intended to turn judges into jurors" or to require them to "weigh or choose between conflicting scientific opinions." *Joiner*, 78 F.3d at 530.

- Consistent with Chief Justice Rehnquist's observation, in his partial dissent in *Daubert*, that the Federal Rules do not impose on trial judges "the obligation or the authority to become amateur scientists," the Eleventh Circuit warned that the "gatekeeping role" is "not intended to turn judges into . . . surrogate scientists" or to require them to "analyze or study the science in question in order to reach [their] own scientific conclusions from the material in the field." *Joiner*, 78 F.3d at 530.

III.

PETITIONERS AND THEIR *AMICI* ARE ATTEMPTING TO TURN *DAUBERT* ON ITS HEAD AND CREATE A HEIGHTENED STANDARD FOR THE ADMISSIBILITY OF SCIENTIFIC TESTIMONY THAT WOULD REQUIRE TRIAL JUDGES TO ACT AS JURORS AND AMATEUR SCIENTISTS.

Although the question before the Court is the appropriate standard of appellate review of district court decisions excluding expert scientific testimony under *Daubert*, Petitioners and their *amici* argue extensively — and, as we have shown, incorrectly — that the Eleventh Circuit misread and misapplied *Daubert*'s teachings. In so doing, they attempt to turn *Daubert* on its head, offering a skewed interpretation of the case that would, if adopted, create a heightened standard for the admissibility of expert scientific testimony that would require trial judges to assume the roles of jurors and "amateur scientists." Indeed, Petitioners and their *amici* act as if Rule 702 and *Daubert*: (a) raised the standard for admissibility of expert scientific testimony; (b) directed that the admissibility determination depends upon the conclusions of the expert; (c) established a rigid and definitive checklist for determining whether expert testimony is reliable; and (d) authorized trial judges to exclude scientific testimony from evidence if they find it unpersuasive.

A. Petitioners And Their *Amici* Wrongly Act As If *Daubert* Rejected The Federal Rules Of Evidence.

Although this Court unequivocally rejected the rigid "general acceptance" test in *Daubert* and adopted, consistent with the liberal thrust of the Federal Rules, a more "relaxed" approach to deciding the admissibility of expert scientific testimony, Petitioners and their *amici* ignore these principles

and assert that *Daubert* imposed "formidable burdens" on the proponents of such testimony, and "clearly requires that judges subject expert evidence to more penetrating pretrial scrutiny." *See, e.g., Brief Of The Dow Chemical Company* at 13 (arguing "*Daubert* imposes formidable burdens on experts to demonstrate the reliability and relevance of their theories to the satisfaction of the district court"); *Brief Of The American Medical Association* at 10 (asserting that "contrary" to endorsing a more "liberal" or "permissive" approach to the admissibility of expert scientific testimony, "*Daubert* clearly requires trial judges to subject expert evidence to more penetrating pretrial scrutiny"); *Brief Of The Pharmaceutical Research And Manufacturers Of America* at 9, 21 (claiming *Daubert* requires that "a trial court must scrutinize each aspect of the methodology that an expert uses to reach a conclusion" as part of the "complex inquiry that district courts must conduct under Rule 702"); *Brief Of The Chamber Of Commerce Of The United States Of America* at 27 (arguing the "core of *Daubert* is its requirement for an intensive analysis of both the methodology and reasoning underlying the expert's opinion").

There is no support in Rule 702 or *Daubert* for these statements of a heightened admissibility test. *See Daubert*, 509 U.S. at 587-88. Similarly, most circuit courts have followed *Daubert* in observing that a stringent admissibility test is inconsistent with the "permissive backdrop" of the Federal Rules of Evidence.[2]

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2. *See, e.g., Joiner*, 78 F.3d at 529-530; *Borawick v. Shay*, 68 F.3d 597, 610 (2nd Cir. 1996) ("by loosening the strictures on scientific evidence set by *Frye*, *Daubert* reinforces the idea that there should be a presumption of admissibility of evidence"); *McCullock*, 61 F.3d at 1042 ("*Frye's* rigid standard was inconsistent with the liberal thrust of the federal rules"); *In Re Paoli Railroad Yard PCB Litigation*, 35 F.3d 717, 741 (3rd Cir. 1994) (noted *Daubert*'s rejection of the *Frye* test and its endorsement of "Rule 702's liberal policy of admissibility"), *cert. denied*, 115 S. Ct. 1253 (1995); *United States v. Jones*, 107 F.3d 1147, 1156 (6th Cir. 1997) (observing *Daubert*'s rejection (Cont'd)

B. Petitioners And Their *Amici* Wrongly Act As If *Daubert* Held That Admissibility Depends Upon The Expert's Conclusions.

In arguing that the Eleventh Circuit misinterpreted *Daubert*, several of Petitioners' *amici* blatantly disregard the bright line this Court drew between a scientist's methodology — which *should* be considered in determining admissibility — and his conclusions — which *should not* be considered. They incorrectly assert that the methodology-conclusion distinction is "artificial" and has been rejected by "most courts." *See, e.g., Brief Of The New England Journal Of Medicine* at 16 (arguing that "any distinction between methodology and conclusions is artificial"); *Brief Of The Dow Chemical Company* at 16-17 (citing two cases for the proposition that "most cases applying *Daubert* have agreed that the distinction between methodology and conclusions upon which the Eleventh Circuit relied so heavily has only limited practical import"); *Brief For The United States* at 26 (asserting *Daubert* "mandated" that trial judges determine the "analytical gap" between an expert's "conclusions and the scientific materials on which they purportedly relied"); *Brief Of Chemical Manufacturers Association* at 15, 17 (stating that under Rule 702 a court may focus on methodology and the

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of the "general acceptance" standard and noting the "relaxed standard in Rule 702 governing expert scientific testimony"); *United States v. Davis*, 40 F.3d 1069, 1073, n.4 (10th Cir. 1994) (noting that *Daubert* "has replaced the historical *Frye*" standard, and observing that the new standard adopts the "liberal thrust" of the Federal Rules); *Ambrosini v. Labarraque*, 101 F.3d 129, 133 (D.C. Cir. 1996) (noting *Daubert*'s rejection of the "rigid" *Frye* test, and adoption of an approach consistent with the "liberal thrust" of the Federal Rules). *See also*, Cranor, *Judicial Boundary Drawing And The Need For Context-Sensitive Science in Toxic Torts After Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 16 Va. Environ. L.J. at 1, 13 (Fall 1996) ("In *Daubert*, the Supreme Court appears to have rendered an opinion liberalizing the standard for the admissibility of scientific evidence").

"conclusions themselves"). *Amici*'s arguments are contrary to the admonition by this Court — and the holdings of most circuit courts — that the "focus" of the reliability assessment be "solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 596.[3]

The trial judge's assessment of an expert's methodology should be no more complex than asking whether the way in which the expert went about reaching his conclusion — his

3. The majority of circuit courts have followed this Court's instruction that the reliability inquiry entails an examination only of the soundness of the methodology employed by the proposed expert, not of the expert's conclusions. *See, e.g., Joiner*, 78 F.3d at 530; *In re Joint Eastern and Southern District Asbestos Litigation*, 52 F.3d 1124, 1132 (2nd Cir. 1995) (emphasizing that the trial judge must not "cross the line" between evaluating an expert's methodology and the strength of his conclusions); *In re Paoli*, 35 F.3d at 744 (the analytical focus "must be solely on principles and methodology"); *Smelser v. Norfolk Southern Railway Company*, 105 F.3d 299, 303 (6th Cir. 1997) ("when considering reliability, the trial court must focus on the soundness of the expert's methodology and not the correctness of his conclusions"); *Cummins v. Lyle Industries*, 93 F.3d 362, 368 (7th Cir. 1996) ("the focus must be solely on principles and methodology, not the conclusions they generate"); *Hopkins v. Dow Corning Corporation*, 33 F.3d 1116, 1124 (9th Cir. 1994) (the "inquiry must be solely on principles and methodology"), *cert. denied*, 115 S. Ct. 734 (1995); *Compton v. Subaru of America, Inc.*, 82 F.3d 1513, 1518 (10th Cir. 1996) (the focus "must be solely on principles and methodology"); *Ambrosini*, 101 F.3d at 134 ("Under the first prong of the analysis, the district court's focus is on the methodology or reasoning employed"). *See also*, Mills, *Daubert v. Merrell Dow Pharmaceuticals, Inc., On Remand: The Ninth Circuit Loses Its Way In The 'Brave New World'*, 26 Ga. L. Rev. at 849, 874-75 (1995) ("Nowhere does the [*Daubert*] court imply that lower courts should even consider the substance of the expert's conclusion when determining admissibility under Rule 702"); Chesebro, *Taking Daubert's Focus Seriously: The Methodology/Conclusion Distinction*, 15 Cardozo L. Rev. at 1747, 1748 (1994) ("It is completely inappropriate . . . to advance Rule 702 admissibility arguments that depend upon the ultimate conclusion reached by the expert").

reasoning, his analytical approach — is grounded in sound scientific principles. Neither Rule 702 nor *Daubert* permit a trial judge to exclude expert testimony simply because the expert's opinion — or even his approach — is not "generally accepted."[4] Moreover, as long as the methodology employed by the expert is scientifically valid, claims that the expert made errors in applying the methodology and thereby reached the wrong conclusion simply go to the weight of the testimony. As Judge Becker observed in *In re Paoli*: "[T]he judge should not exclude evidence simply because he or she thinks there is a flaw in the expert's investigative process which renders the expert's conclusions incorrect." 35 F.3d at 746.

In *Daubert*, this Court drew a sharp distinction between methodology and conclusion recognizing that an admissibility rule that permits or directs trial judges to determine the flaws in or the correctness of an expert's conclusions would unavoidably intrude upon the "ageless role of the jury." *McCullock*, 61 F.3d at 1045. When a court rejects scientific testimony on the grounds that an expert's methodology is inconsistent with the conclusions of most other experts, or because the judge perceives that the "analytical gap" between the expert's reasoning and his conclusions is "too wide," the judge is rendering a decision based

4. *See, e.g., McCullock*, 61 F.3d at 1042 ("*Daubert* granted the trial judge the discretion and authority to determine whether scientific evidence is trustworthy, even if the technique involved had not yet won general scientific acclaim"); *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1319, n.11 (9th Cir. 1995) ("The focus under *Daubert* is on the reliability of the methodology, and in addressing that question the court and the parties are not limited to what is generally accepted; methods accepted by a minority in the scientific community may well be sufficient"), *cert. denied*, 116 S. Ct. 189 (1995); *Braun v. Lorillard, Inc.*, 84 F.3d 230, 234 (7th Cir. 1996) ("The opinion evidence of reputable scientists is admissible in evidence in a federal trial even if the particular methods they used in arriving at their opinion are not yet accepted as canonical in their branch of the scientific community") *cert. denied*, 117 S. Ct. 480 (1996).

on his perceived strength of the testimony. While consideration of the strength of the proffered testimony may be appropriate in the context of deciding motions for summary judgment or directed verdict, such an assessment of the evidence is not proper in the context of ruling on admissibility. As the Eleventh Circuit properly observed, the "gatekeeping" role is "not intended to turn judges into jurors" or to require them to "weigh or choose between conflicting scientific opinions." *Joiner*, 78 F.3d at 530.

Allowing trial judges to determine the accuracy of an expert's scientific conclusions would have the additional and unfortunate consequence of turning judges into "amateur" or "surrogate" scientists. *Daubert*, 509 U.S. at 600 (partial dissent by Chief Justice Rehnquist); *Joiner*, 78 F.3d at 530. The courtroom is, of course, not a laboratory, and judges are neither trained nor authorized to make "scientific" conclusions.[5] As much as some scientific and

5. Implicit in the Federal Rules of Evidence is the distance trial judges are expected to maintain from scientific analysis and conclusions. Rule 706, for example, permits district courts to appoint neutral scientific advisors to assist the court and the jury in understanding and applying scientific information. Fed. R. Evid. 706. Several Petitioners' *amici*, including The New England Journal of Medicine and The Dow Chemical Company, recommend an increased use of Rule 706 to assist judges in rendering admissibility decisions, and point to *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387 (D. Or. 1996) as a model of how federal judges can effectively use court-appointed scientists to exclude expert testimony. *See Brief Of The New England Journal Of Medicine* at 2, 18-19; *Brief Of The Dow Chemical Company* at 2-3. *Hall* is, however, an abysmal example of the use of court-appointed experts in the context of a *Daubert* inquiry. The judge in *Hall* appointed "neutral" scientists to assist him in determining the admissibility of expert scientific testimony offered by plaintiffs in support of their claims that silicone-gel breast implants caused their illnesses and then excluded the testimony of all of plaintiffs' experts. In so doing, the district court inexplicably *disregarded the opinions of several of his scientific advisors* that the methodologies employed by plaintiffs' experts *were reliable*. 947 F. Supp. at 1446, 1448-51, 1470, 1472-73. Although the same or substantially similar expert testimony has been admitted in dozens of breast implant cases

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medical organizations wish to infuse all federal judges with scientists' sensibilities and priorities, it is neither feasible nor desirable. For example, *amicus* The New England Journal of Medicine states that the task of the Journal's executive editor, Marsha Angell, M.D., in deciding "what medical research studies are admitted into the scientific literature," is "analogous" to the gatekeeping role performed by trial judges in determining the admissibility of scientific evidence. *Brief Of The New England Journal Of Medicine* at 2-3. With all due respect to Dr. Angell and her colleagues, their job bears no meaningful resemblance to the responsibility of a federal trial judge in deciding whether a sick or injured plaintiff will be permitted to present his or her claims to a jury. Unlike the deliberative scientific process and the political and bureaucratic system of journal publication, the universe in which trial judges, lawyers and litigants operate involves human beings with immediate problems, statutes of limitation, unique burdens of proof, and separate roles for judges and juries. Moreover, when the New England Journal of Medicine rejects a study, the author is free to submit his work to another publication. Plaintiffs, of course, do not get a second bite of the apple. As imperfect as it may be, there is no place in the adversarial jury system for trial judges to take on the additional burden of being "amateur scientists."

C. Petitioners And Their *Amici* Wrongly Act As If *Daubert* Established A Rigid And Definitive Checklist For Deciding Whether Expert Testimony Is Reliable.

Petitioners and their *amici* also ignore *Daubert*'s direction that the district court's inquiry into the validity of a scientific

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throughout the country, the judge in *Hall* premised his ruling on his misplaced beliefs that the "interjection of the *Daubert* standards into the screening process for proposed scientific evidence has *substantially heightened the scrutiny* through which such evidence must pass," that the distinction between methodology and conclusion is "*superficial*," and that "the issue before the court . . . is *causation*." *Id.* at 1401, 1415 (emphasis added).

expert's methodology is to be a "flexible one." *Daubert*, 509 U.S. at 593-94. Instead, they argue that scientific testimony must satisfy each of the four factors mentioned in *Daubert*'s "general observations" about reliability — testability, publication/peer review, error rate and general acceptance — in order to be admissible. For example, Petitioners complain that the Eleventh Circuit erred in finding that "the extensive experience and specialized expertise of each of these experts *augment* the reliability of their reasoning and methodology," *Joiner*, 78 F.3d at 532 (emphasis added), because it considered "a factor not even listed by this Court in *Daubert*." *Brief Of Petitioners* at 46.[6] *See also, Brief Of The Pharmaceutical Research Manufacturers Of America* at 7-8 (arguing that the "four factors" described in *Daubert* "must be applied with rigor to carry out *Daubert*'s gatekeeping mandate properly.")

Far from "mandating" bright-line criteria for evaluating the reliability of expert scientific testimony, *Daubert* did "not presume to set out a definitive checklist or test." *Daubert*, 509 U.S. at 593-94. Although the Court clearly intended its "general observations" to be just that, and though most circuit courts have read the "observations" to be illustrative and not exhaustive or applicable in every factual situation[7], opponents of the admission

6. Contrary to Petitioners' suggestion that the Eleventh Circuit focused exclusively, or too greatly, on the "extensive experience and specialized expertise" of the experts, the Court of Appeals clearly considered these factors in addition to, or augmenting, its review of the experts' reasoning and methodologies. *Joiner*, 78 F.3d at 532 ("While this factor is most pertinent in deciding the separate question of whether the experts are qualified to testify, see Fed.R.Evid. 702, it also has some bearing on the determination of the reliability of the underlying reasoning or methodology").

7. Most circuit court decisions have followed *Daubert*'s direction that the methodology inquiry is to be to a "flexible one." *See, e.g., Joiner*, 78 F.3d at 530; *Borawick*, 68 F.3d at 610 (*Daubert* "emphasizes the need for flexibility
(Cont'd)

of scientific evidence, such as Petitioners and their *amici*, repeatedly urge trial courts to exclude testimony that does not comply with the "*Daubert* factors."

In his partial dissent in *Daubert*, Chief Justice Rehnquist foresaw the potential for misunderstanding and misuse of the Court's "general observations": "General observations by this Court customarily carry great weight with lower federal courts, but the ones offered here suffer from the flaw common to most such observations — they are not applied to deciding whether particular testimony was or was not admissible, therefore they tend to be not only general, but vague and abstract." *Daubert*, 509 U.S. at 598.[8] The Court should use this occasion to again "stress the flexibility" of the admissibility inquiry described in *Daubert*. Strict application of the Court's "general observations"

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in assessing whether evidence is admissible," permitting "the trial judge to weigh the various considerations pertinent to the issue in question"); *In re Paoli*, 35 F.3d at 742 ("And *Daubert*, like *Downing*, indicates that the inquiry as to whether particular scientific technique or method is reliable is a flexible one"); *Benedi v. McNeil-P.P.C.*, 66 F.3d 1378, 1383 (4th Cir. 1995) (in "offering these guidelines, the [*Daubert*] court emphasized that it was not formulating a rigid test or checklist, relying instead on the ability of the federal judges to properly determine admissibility"); *Daubert*, 43 F.3d at 1316-17 (9th Cir. 1994) (reading *Daubert*'s "general observations" as "illustrative rather than exhaustive; similarly we do not deem each of them to be equally applicable (or applicable at all) in every case"); *Ambrosini*, 101 F.3d at 133-34 (emphasizing that the methodology inquiry is a "flexible one" and that "none of the factors discussed is necessarily applicable in every case or dispositive; nor are the four factors exhaustive").

8. *See also*, Cranor, *supra* at n.2 at 14 ("The Court did stress the flexibility of the trial court examination of the question, but, in assigning the daunting task of ruling on the admissibility of extremely complicated, technical, and sometimes novel scientific techniques, it may have tempted trial judges to look at a set of fixed criteria to handle this difficult procedure").

would result in the heightened admissibility test advocated by Petitioners and their *amici* and would prevent reliable and relevant scientific evidence from being heard by juries.[9]

D. Petitioners And Their *Amici* Wrongly Act As If *Daubert* Authorized Trial Judges To Exclude Scientific Testimony From Evidence If They Find It Unpersuasive.

Finally, Petitioners and their *amici* disregard the distinction this Court drew in *Daubert* between the admissibility of evidence and its sufficiency. In so doing, they essentially act as if *Daubert* authorized trial judges to simply exclude scientific testimony from evidence if they find it unpersuasive. This Court in *Daubert* held precisely the opposite — finding the defendant "overly pessimistic about the capabilities of the jury and the adversary system generally." *Daubert*, 509 U.S. at 595-96.

9. Some of Petitioners' *amici* would further restrict the *Daubert* admissibility by limiting the kind of scientific evidence an expert may rely upon in formulating his opinions. They would restrict such evidence to epidemiological studies, and bar such other reliable scientific evidence as animal studies, *in vitro* studies, medical diagnoses and case reports. *See, e.g., Brief Of The New England Journal Of Medicine* at 9 (arguing only epidemiological studies can establish a "link between a risk factor and a disease" in the "first place"); *Brief Of The American Medical Association* at 11-15 (suggesting that disease causation can only be shown if there is determinative epidemiology); *Brief Of The Pharmaceutical Research And Manufacturers Of America* at 11 (arguing that "animal studies, without confirmation through rigorous epidemiological or evidence in humans, do not provide a sufficient basis for an expert to assert causation in humans"). There is no support in the Federal Rules or *Daubert* for such limitations on the types of evidence that an expert may rely upon to satisfy the *Daubert* test. *See, e.g., Benedi*, 66 F.3d at 1384 ("We do not read *Daubert* as restricting expert testimony to opinions that are based solely upon epidemiological data"); *In re Paoli*, 35 F.3d at 758-59 (admitting expert testimony based on differential diagnosis, and not epidemiology); *Hopkins*, 33 F.3d at 1124 (permitting experts to base their opinions on scientific data and techniques "relied upon by medical experts in making determinations regarding toxic causation where there is no solid body of epidemiological data to review").

As a practical matter, the "conclusions" of scientific witnesses (at least in toxic tort cases) typically concern, directly or indirectly, whether a particular substance can and/or did cause a disease or adverse condition in one exposed to the substance. The question of causation is, unlike the admissibility issue, a matter of the "sufficiency" of the totality of a plaintiff's evidence. *See, e.g., In re Joint Eastern and Southern District Asbestos Litigation*, 52 F.3d at 1133 ("Unlike admissibility assessments, which involve decisions about individual pieces of evidence, sufficiency assessments entail a review of the sum total of a plaintiff's evidence").

In *Asbestos Litigation*, the Second Circuit emphasized the distinction between the trial court's role in "assessing the admissibility of scientific evidence in federal court as articulated by the Supreme Court in *Daubert*," and its consideration of the "sufficiency of scientific evidence" that bears on the factual issue of causation. 52 F.3d at 1131-32. The district court entered judgment as a matter of law in favor of the defendants following the jury's verdict that the plaintiff had died of colon cancer caused by asbestos exposure. The trial court based its ruling on its independent assessment of the plaintiff's evidence and expert testimony. *Id.* at 1130. The Second Circuit reversed, holding that the "district court overstepped the boundaries set forth in *Daubert*. It impermissibly crossed the line from assessing evidentiary reliability to usurping the role of the jury." *Id.* at 1131. In so ruling, the court pointed out that:

> "[A]dmissibility" and "sufficiency" of scientific evidence necessitate different inquires and involve different stakes. Admissibility entails a threshold inquiry over whether a certain piece of evidence ought to be admitted at trial. The *Daubert* opinion was primarily about admissibility. It focused on the district court's role in evaluating the methodology and the applicability of contested scientific evidence in admissibility decisions.

Id. at 1132. In contrast, the court's "sufficiency inquiry, which asks whether the collective weight of a litigant's evidence is adequate to present a jury question, lies further down the litigational road." *Id.*[10]

This Court in *Daubert* emphasized that the reliability-relevance admissibility standard is *not* intended to replace such "traditional" devices for challenging the sufficiency of scientific evidence as cross-examination, the presentation of contrary evidence, and thoughtful instruction on the burden of proof. *Daubert*, 509 U.S. at 595-96. Petitioners and their *amici* would have trial judges assess the sufficiency of a plaintiff's scientific evidence, including the conclusions of her experts, during pre-trial admissibility hearings. Indeed, the argument of Petitioners and their *amici* boils down to the proposition that the expert

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10. *See Joiner*, 78 F.3d at 534 (Circuit Judge Birch, in a special concurrence, stated that the "sufficiency of the evidence and the weight of the evidence, however, are beyond the scope of the *Daubert* analysis" and that whether the "conclusions advanced from the stated premises in fact follow and the persuasiveness of those conclusions in the ultimate resolution of competing opinions, are questions appropriately left to the finder of fact"); *McCullock*, 61 F.3d at 1045 (the trial court should limit its admissibility inquiry to the questions of methodology and relevance, and avoid "evaluating witness credibility and weight of the evidence, the ageless role for the jury"); *Benedi*, 66 F.3d at 1383-84 (the focus of the court's inquiry is or methodology, leaving it to the jury to "assess the weight and credibility of the evidence"); *Ambrosini*, 101 F.3d at 1135-36 (an expert's testimony "does not warrant exclusion simply because it fails to establish the causal link to a specified degree of probability"). *See also*, Mills, *supra* at n.3 at 875 (Rule 702 "does not require that the testimony be sufficient to carry the plaintiff's burden of proof at trial").

testimony offered by the plaintiffs in the underlying action consists of "absurd and irrational pseudoscientific assertions" because they are based on an insufficient number of animal studies and wrong-headed conclusions by the experts. Even if that argument were correct, this Court in *Daubert* held that it is for the jury and the adversary system, not the trial judge, to make such a determination. Moreover, if the "scintilla" of evidence introduced by the plaintiffs is really insufficient, directed verdict or summary judgment may be proper, but "wholesale exclusion" under Rule 702 is not. *Daubert*, 509 U.S. at 596.

IV.

THIS COURT SHOULD RE-EMPHASIZE THAT THE FEDERAL RULES "RELAXED" THE STANDARD FOR THE ADMISSIBILITY OF EXPERT SCIENTIFIC TESTIMONY AND THAT THE TRIAL JUDGE'S GATEKEEPING ROLE IS A LIMITED ONE.

To achieve judicial uniformity in admitting scientific expert testimony, and to avoid the inappropriate exclusion of reliable and relevant testimony, the Court should re-emphasize the limited nature of the trial court's gatekeeping function articulated in *Daubert*. Despite the seemingly clear message of *Daubert*, Petitioners and their *amici* offer a distorted version of the reliability-relevancy admissibility test that would permit, if not obligate, trial judges to dispose of entire litigations in the context of what is supposed to be "a preliminary assessment" of the admissibility of scientific evidence. In effect, Petitioners and their *amici* urge adoption of a heightened standard for the admissibility of expert scientific testimony that would provide unprecedented litigation protection for manufacturers and distributors of pharmaceuticals, medical devices and toxic chemicals. Indeed, they promote a drastic revision of the Federal Rules of Evidence, the Federal Rules of Civil

Procedure, and the historical (and constitutionally mandated) relationship between judge and jury.

Moreover, as the proceedings below and numerous other district court cases illustrate, the approach suggested by Petitioners and *amici* would convert simple admissibility hearings — held either prior to trial or during trial as testimony is introduced — into elaborate and expensive bench mini-trials.[11] Neither the Federal Rules nor this Court in *Daubert* intended or foresaw that, in order for a plaintiff to present her case to a jury, she would first have prove her case to a judge through presentation of all of her scientific evidence and expert testimony. Neither the Federal Rules nor this Court in *Daubert* anticipated that trial judges would use such proceedings to render findings on the conclusions of the experts and the sufficiency of a plaintiff's evidence. Neither the Federal Rules nor this Court in *Daubert* contemplated that threshold admissibility hearings would evolve into summary judgment-like hearings during which the procedural protections typically afforded to plaintiffs in actual summary judgment proceedings are ignored.[12] Neither

11. *See, e.g., In re TMI Litig. Cases Consol. II*, 911 F. Supp. 775, 785-86 (M.D. Pa. 1996) and *In re TMI Litig. Cases Consol. II*, 922 F. Supp. 977, 1000 (M.D. Pa. 1996) (multiple *Daubert* hearings conducted over the course of twenty days, with testimony from more than two dozen experts, as well as the submission of voluminous scientific literature and documentary evidence); *Hall*, 947 F. Supp. 1393 (evidentiary hearing "spanned four intense days" during which the court heard the testimony of numerous scientists, and received into evidence the reports from court-appointed experts and voluminous literature and internal company documents); *Wade-Greaux v. Whitehall Laboratories, Inc.*, 874 F. Supp. 1441, 1448 (D. V.I. 1994) (the court conducted an admissibility hearing under *Daubert* "spanning seven separate days," during which testimony was "adduced from each of the plaintiffs' expert witnesses" who were "required to address both general causation and specific causation"), *aff'd*, 46 F.3d 1120 (3rd Cir. 1994).

12. In evaluating the "collective weight of a litigant's evidence" in the (Cont'd)

the Federal Rules nor this Court intended that admissibility hearings under *Daubert* would become so time-consuming and expensive — essentially requiring two trials — that sick and injured citizens would face new barriers to the courthouse. Under such a regime, individual plaintiffs could not hope to compete with the wealthy institutions and corporations on the other side.

The heightened scrutiny of proffered expert scientific testimony proposed by Petitioners and their *amici* would allow judges to substitute their judgment for a jury's in the guise of evaluating each microscopic step of a scientist's analysis. Such a process is contrary to Rule 702 and this Court's holding in *Daubert*, as well as to the constitutionally protected right to a jury trial. That being so, we respectfully submit that, whatever standard of review the Court finds applicable in this case, the Court should re-emphasize that the Federal Rules "relaxed" the standard for the admissibility of expert scientific testimony and that the trial judge's gatekeeping role is a limited one.

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context of a motion for summary judgment or directed verdict, the trial judge "must view the evidence in the light most favorable to the non-movant and grant that party every reasonable inference that the jury might have drawn in its favor," and must "not assess the weight of conflicting evidence, or the credibility of the witnesses, or substitute its judgement for that of the jury." *In re Joint Eastern and Southern District Asbestos Litigation*, 52 F.3d at 1131.

CONCLUSION

The judgment of the United States Court of Appeals for the Eleventh Circuit should be affirmed.

Respectfully submitted,

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